

Notice of Allowability

Application No.

09/754,998

Examiner

Susan Ungar

Applicant(s)

RINDERKNECHT ET AL.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to the amendment filed June 30, 2005.
2. ☐ The allowed claim(s) is/are 30, 28, 29, now renumbered 1-3, respectively.
3. ☒ The drawings filed on 04 January 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

SPO

2. The Amendment filed June 30, 2005 in response to the Office Action of January 3, 2005 is acknowledged and has been entered. Claims 28 and 30 have been amended and claim 29 is hereby rejoined to the examined invention. Claims 28-30 are currently under prosecution.

3. The application has been amended as follows:

In the claims:

Claim 30 was amended as follows: on line 2 of the claim, after the phrase "and a mixture of" the phrase ""an antibody fragment" was deleted and the phrase -- antibody fragments -- was substituted.

Claim 30 was amended as follows: on line 3 of the claim, after the phrase "light and heavy chains and" the phrase "the antibody fragment" was deleted and the phrase -- antibody fragments -- was substituted.

Claim 30 was amended as follows: on line 4 of the claim, after the phrase "light and heavy chains, wherein" the phrase " the purity of the antibody fragment comprising correctly disulfide linked light and heavy chains in the composition is at least about 95%" was deleted and --at least about 95% of said antibody fragments in said composition comprise correctly disulfide linked light and heavy chains,-- was substituted.

Claim 30 was amended as follows: on line 6 of the claim after the phrase "the antibody" the term "fragment" was deleted and the phrase --fragments are-- was substituted.

4. Authorization for this Examiner's Amendment was given in a telephone interview with Diedre Conley on September 14, 2005.

5. The following is an Examiner's Statement of Reasons for Allowance:

In view of the amendment of claim 30, claims 30 and 28 are free of the art and allowable. Upon the allowance of the generic claim, applicant is entitled to consideration of claims to the additional species, antibody fragments that bind CD18 of claim 29, that was previously withdrawn from consideration because the additional species is written in dependent form or otherwise includes all the limitations of the allowed generic claim (see 37 CFR 1.141). Search of claim 29 has revealed that claim 29 is free of the art as the prior art neither teaches nor suggests a composition comprising anti-CD18 antibody fragments wherein the composition comprises at least about 95% correctly disulfide linked light and heavy chains and also comprises incorrectly disulfide linked light and heavy chains. The closest prior art is US Patent No. 5,747,035 which discloses anti-CD18 antibody fragment products purified by a combination of SDS PAGE and two different HPLC methods but does not teach compositions comprising at least about

95% correctly disulfide linked light and heavy chains which also comprise incorrectly disulfide linked light and heavy chains.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Susan Ungar
Primary Patent Examiner
September 15, 2005

